development, neither the sequence nor the function of syncytin was known at the time of filing.

The Office Action asserts, "To be specific, the application must teach the skilled artisan in specific terms specific biological activities of the retroviral RNA molecule, and reasonably correlate that activity to a disease condition." Applicants respectfully submit that the Office Action is incorrectly applying the specific utility standard set forth in the MPEP.

MPEP §2107.01(I)(A) provides:

> A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

Contrary to the Office Actions assertions, this section of the MPEP does not set forth that an applicant must disclose a specific biological activity and reasonably correlate that activity to a disease condition to meet the specific utility test. Rather, it teaches that when an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition, the applicant has established a specific utility. However, it does not mandate that these are the only acceptable conditions for a finding of specific utility. In fact, the only situation specifically set forth in this section that the MPEP asserts does not meet the specific utility test are general statements of diagnosing an unspecified disease.

The MPEP relies heavily on the *In re Fisher* decision in its sections regarding utility. *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The claims at issue in *Fisher* were directed to expressed sequence tags (ESTs). The court stated:

> The claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant's] research effort, but only tools to be used along the way in the search for a practical utility...[Applicant] does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

Id. at 1376.

The facts relevant to the present claims are different from *Fisher*. For example, the entire sequence of HERV-W is disclosed, whereas *Fisher* was concerned with ESTs—very short portions of the underlying genes. The underlying genes in *Fisher* had no known or asserted function or utility; in the present application there is discussion of phylogenetic analysis of the claimed sequence that correlates portions of the sequence to known retroviral elements with known functions. Thus, the specification reveals much more about the structure and function of the claimed sequence than was found in *Fisher*.

Fisher establishes that the following asserted uses for a claimed nucleotide sequence are not considered specific to the claimed sequence because they are applicable to many nucleotide sequences:

- use as a molecular marker;
- used to measure the level of mRNA in a tissue sample via microarray technology to provide information about gene expression;
- used to provide a source for primers for use in PCR to enable rapid and inexpensive duplication of specific genes;
- used to identify the presence or absence of a polymorphism;
- used to isolate promoters via chromosome walking;
- used to control protein expression; and
- used to locate genetic molecules of other plants and organisms.

See In re Fisher, 421 F.3d 1365, 1368 (Fed. Cir. 2005).

To show substantial utility, an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after

further research. "Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

Contrary to the allegations made by the Office Action, Applicants' disclosure asserts a number of utilities for the subject matter of claim 1:

> The nucleic material, the nucleotide sequences and the peptides or proteins which may be expressed by said materials and sequences may be used to detect, predict, treat and monitor any autoimmune disease, and the pathologies which are associated with it, as well as in cases of pathological pregnancy or of unsuccessful pregnancy.

See paragraph [0195] of the published application. The specification also indicates that the nucleic material, or a nucleotide fragment thereof, or a peptide encoded by the nucleic material or fragment thereof may be used as molecular, chromosomal, and/or proximity markers, and may be used as molecular labels for autoimmune diseases, pathological pregnancies, and unsuccessful pregnancies. *See* paragraphs [0060] to [0064]. The specification further discloses that "autoimmune" is understood to mean in particular: multiple sclerosis, rheumatoid arthritis, disseminated lupus erythematosus, insulin-dependent diabetes, and/or pathologies that are associated with them. *See* paragraphs [0020] to [0025].

Applicants respectfully disagree with the Office Action's position that the utilities asserted in the specification are not substantial or specific. First, the ability to detect, predict, treat, and/or monitor a specific pathological condition is a substantial utility according to the MPEP. For example, MPEP §2107.01(I)(B) states, "An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring." Also, MPEP §2107.01(III) discusses a number of Federal Circuit decisions holding that compounds having therapeutic or

pharmacological activity provide an immediate benefit to the public or, in other words, a substantial utility, even if "an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition."

Second, the Office Action's position that, "Assertions that HERV-w can be used to treat an autoimmune disease or pathological pregnancy are directed at generic and thus unspecified condition," disregards the fact that the specification indicates that "autoimmune" means in particular multiple sclerosis, rheumatoid arthritis, disseminated lupus erythematosus, insulin-dependent diabetes, and/or pathologies that are associated with them. *See* specification, paragraphs [0020] to [0025]. Certainly, at least multiple sclerosis, rheumatoid arthritis, disseminated lupus erythematosus, and insulin-dependent diabetes are specific, not general, conditions.

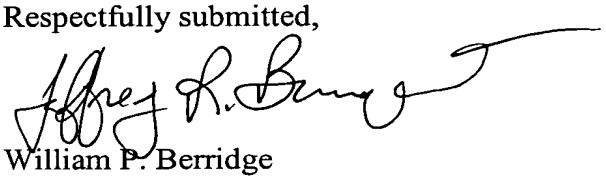
A number of studies conducted prior to the filing date of the application implicate the presence of endogenous retroviral sequences in human genes in connection with a number of human diseases. Two of the review articles expound upon the importance of HERV research due to the significant pathological potential of HERV sequences incorporated into human genes. *See* Lower et al., "The viruses in all of us: Characteristics and biological significance of human endogenous retrovirus sequences," Proc. Natl. Acad. Sci. USA, 93:5177–84 (1996); Urnovitz et al., "Human Endogenous Retroviruses: Nature, Occurrence, and Clinical Implications in Human Disease," Clinical Microbiology Reviews, 9(1):72–99 (1996). For example, Urnovitz et al. state, "Currently, there is an urgent need to develop diagnostic markers for the occurrence of HERVs in both health and disease." *See* page 95, 2nd column. Lower et al. discuss the importance for (1) the search for complete proviruses for new and partially characterized HERVs; and (2) continued studies to investigate the expression of HERV genes at the RNA and protein level. *See* page 5183, 2nd column.

The specification clearly discloses and evidences that SEQ ID NO:11 is the DNA complement to a putative endogenous retroviral genomic RNA sequence (HERV-W). In view of the teachings of Lower and Urnovitz, one of skill in the art, at the time of the invention, would have immediately recognized the specific and substantial utility of a newly discovered HERV based on the characteristics known at that time to be common to HERVs. "The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

In view of the foregoing, reconsideration and withdrawal of the rejections are respectfully requested.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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